RESEARCH PROTOCOL SAFETY SURVEY
Louis Stokes Cleveland DVA Medical Center (541)

PRINCIPAL INVESTIGATOR (PI):
PROJECT TITLE:
PROTOCOL #:
DATE OF SUBMISSION:
LIST VA LOCATIONS IN WHICH PI CONDUCTS RESEARCH:
LIST NON-VA LOCATIONS IN WHICH PI CONDUCTS RESEARCH:

1. DOES THE RESEARCH INVOLVE THE USE OF ANY OF THE FOLLOWING?

a. Biological Hazards (Microbiological or viral agents, pathogens, toxins, select agents as defined in Title 42 Code of Federal Regulations (CFR) 72.6) YES ☐ NO ☐

b. Human or non-human cell or tissue samples (including cultures, tissues, blood, other bodily fluids or cell lines) YES ☐ NO ☐

c. Recombinant deoxyribonucleic acid (DNA) YES ☐ NO ☐

d. Chemicals:
- (1) Toxic chemicals (including heavy metals) YES ☐ NO ☐
- (2) Flammable, explosive, or corrosive chemicals YES ☐ NO ☐
- (3) Carcinogenic, mutagenic, or teratogenic chemicals YES ☐ NO ☐
- (4) Toxic compressed gases YES ☐ NO ☐
- (5) Acetylcholinesterase inhibitors or neurotoxins YES ☐ NO ☐

e. Controlled Substances YES ☐ NO ☐

f. Ionizing Radiation:
- (1) Radioactive materials YES ☐ NO ☐
- (2) Radiation generating equipment YES ☐ NO ☐

g. Nonionizing Radiation:
- (1) Ultraviolet Light YES ☐ NO ☐
- (2) Lasers (class 3b or class 4) YES ☐ NO ☐
- (3) Radiofrequency or microwave sources YES ☐ NO ☐

h. Physical agents, i.e., electricity, trauma, etc. YES ☐ NO ☐

i. Animals (see ***NOTE*** in box below) YES ☐ NO ☐

If the answer to <u>any</u> of these questions is YES, complete all sections of this survey that apply.

If <u>all</u> answers are NO, a documented review by the local Subcommittee on Research Safety is still required prior to submission.

If the research involves the use of human subjects or human tissues, Institutional Review Board (IRB) review is required.

NOTE: *Use of animals also requires submission of an Institutional Animal Care and Use Committee/Subcommittee on Animal Studies-approved Animal Component.*

2. BIOLOGICAL HAZARDS

a. Does your research involve the use of microbiological or viral agents, pathogens, toxins, poisons or venom?
YES ☐ NO ☐ **If NO, skip to section 4 Cells and Tissue Samples.**

If **YES**, list all Biosafety Level 2 and 3 agents or toxins used in your laboratory. It is the responsibility of each PI to:

(1) Consult either:
(a) The National Institutes of Health (NIH)-Center for Disease Control and Prevention (CDC) publication entitled Biosafety in Microbiological and Biomedical Laboratories or
(b) The CDC online reference (http://www.cdc.gov)

(2) Identify the Biosafety Level (also called Risk Group) for each organism, agent, or toxin. Enter it into the following table.

Organism, Agent, or Toxin	Biosafety Level**

** For **each Biosafety Level 2 or 3 agent or toxin** listed, provide the information requested on the following page(s). (Description of Biosafety Levels 2 and 3 can be found in Appendix A.)

b. Are any of the biohazardous agents listed above classified as a "Select Agent" by the Centers for Disease Control? YES ☐ NO ☐

3. BIOLOGICAL HAZARDS (*list separately)* - Description of Use *NOTE: copy this section as necessary.*

a. Identify the microbiological agent or toxin (name, strain, etc.):

_____

b. If this is a Select Agent (42 CFR 72.6), provide the CDC Laboratory Registration # and the date of the CDC inspection:

_____

c. Indicate the largest volume and/or concentration to be used:

_____

d. Indicate whether antibiotic resistance will be expressed, and the nature of this antibiotic resistance:

_____

e. Describe the containment equipment (protective clothing or equipment, biological safety cabinets, fume hoods, containment centrifuges, etc.) to be used in this research: _____

Biological Safety Cabinet: Date of Last Certification:		
Class I: ☐	Class II: ☐	Class III: ☐

f. Describe the proposed methods to be employed in monitoring the health and safety of personnel involved in this research: _____

4. CELLS and TISSUE SAMPLES

a. Will personnel work with animal blood, human or non-human primate blood, body fluids, organs, tissues, cell lines or cell clones? YES ☐ NO ☐ **If NO, skip to section 5 RECOMBINANT DNA.**

If yes, specify: _____

If you are acquiring blood, non-human primate blood, body fluids, organs, tissues, cell lines or cell clones from animals that belong to another investigator, identify the investigator, the protocol title and number: _____

b. Will research studies represent a potential biohazard for lab personnel? NA ☐ YES ☐ NO ☐

If yes, specify the potential hazard and precautions employed to protect personnel in the laboratory:
See section c.

c. Specify precautions employed to protect personnel working in the laboratory: Standard (Universal) Precautions will be taken when working with Human/Non-Human Cell Lines, which includes protective barriers such as gloves, lab coat, protective eyewear, and biological safety cabinet.

***** Human Cell Lines are considered hazardous. Biosafety Level 2 precautions will be followed.***

Biological Safety Cabinet: Date of Last Certification:		
Class I: ☐	Class II: ☐	Class III: ☐

d. Personnel who will work with Biohazard: _____

e. Degree and Nature of risk to personnel: _____

f. Biosafety Level: _____

g. Length of time hazard is considered a risk: _____

h. Means of Decontamination: _____

5. RECOMBINANT DNA

a. Are procedures involving recombinant DNA used in your laboratory? YES ☐ NO ☐ **If NO, skip to section 6 USE OF CHEMICALS.**

b. Are recombinant DNA procedures used in your laboratory limited to PCR amplification of DNA segments (i.e., no subsequent cloning of amplified DNA)? YES ☐ NO ☐

(1) If **YES**, your recombinant DNA studies are exempt from restrictions described in the NIH Guidelines for Research Involving Recombinant DNA Molecules.

(2) If **NO**, it is the responsibility of each PI to:

(a) Consult the current NIH Guidelines for Research Involving Recombinant DNA Molecules which can be found at the Internet site http://www4.od.nih.gov/oba/rac/guidelines/guidelines.htm.

(b) Identify the experimental category of their recombinant DNA research. _____

c. **Description of Recombinant DNA Procedures:**

(1) Identify the NIH classification (and brief description) for these recombinant DNA studies: _____

(2) Biological source of DNA insert or gene: _____

(3) Function of the insert or gene: _____

(4) Vector(s) used or to be used for cloning (e.g., pUC18, pCR3.1): _____

(5) Host cells and/or virus used or to be used for cloning (e.g., bacterial, yeast or viral strain, cell line): _____

(6) Personnel who will work with Biohazard: _____

(7) Degree and Nature of risk to personnel: _____

(8) Biosafety Level: _____

(9) Safety Precaution(s): _____

(10) Length of time hazard is considered a risk: _____

(11) Means of Decontamination:

6. USE OF CHEMICALS

a. Has the use of chemicals in your laboratory been reviewed by an appropriate committee or subcommittee in the past 12 months? YES ☐ NO ☐

b. Are personnel knowledgeable about the special hazards posed by:

(1) Carcinogens?	NA ☐	YES ☐	NO ☐
(2) Teratogens and Mutagens?	NA ☐	YES ☐	NO ☐
(3) Toxic gases?	NA ☐	YES ☐	NO ☐
(4) Neurotoxins?	NA ☐	YES ☐	NO ☐
(5) Reactive and potentially explosive compounds?	NA ☐	YES ☐	NO ☐

NOTE: *Submission of the laboratory chemical inventory is required for local review.*

OSHA AND EPA-REGULATED HAZARDOUS CHEMICALS USED IN PROTOCOL

Chemical	Chemical Class.	Protective Equipment	NFPA Chemical Rating*	Personnel who will work with substance	Storage/ Location	Use/ Location

*NFPA (National Fire Protection Association) Chemical Rating:

HEALTH		
4	**Danger**	May be fatal on short exposure. Specialized protective equipment required
3	**Warning**	Corrosive or toxic. Avoid skin contact or inhalation
2	**Warning**	May be harmful if inhaled or absorbed
1	**Caution**	May be irritating
0		No unusual hazard
NR		Not Rated

FLAMMABILITY		
4	**Danger**	Flammable gas or extremely flammable liquid
3	**Warning**	Flammable liquid flash point below 100° F
2	**Caution**	Combustible liquid flash point of 100° to 200° F
1		Combustible if heated
0		Not combustible
NR		Not Rated

REACTIVITY		
4	**Danger**	Explosive material at room temperature
3	**Danger**	May be explosive if shocked, heated under confinement or mixed with water
2	**Warning**	Unstable or may react violently if mixed with water
1	**Caution**	May react if heated or mixed with water but not violently
0	**Stable**	Not reactive when mixed with water
NR		Not Rated

SPECIAL NOTICE	
W	Water Reactive
Oxy	Oxidizing Agent
NR	Not Rated

Personal and area dosimeters will be used to monitor personnel working with vapor forming chemicals. John Schaffer, Research Safety Coordinator, coordinates monitoring with the facility Safety Officer.

7. CONTROLLED SUBSTANCES

a. Does your research involve the use of any substance regulated by the Drug Enforcement Agency?
YES ☐ NO ☐ **If NO, skip to section 8 RADIOACTIVE MATERIALS.**

If yes, list controlled substances to be used:

(1) _____

(2) _____

(3) _____

(4) _____

(5) _____

(6) _____

b. Are all Schedule II and III drugs stored in a double-locked vault? NA ☐ YES ☐ NO ☐

NOTE: *The schedule of controlled substances can be found at the Internet site* http://www.usdoj.gov/dea/pubs/schedule.pdf

8. RADIOACTIVE MATERIALS

Does your research involve the use of radioactive materials? YES ☐ NO ☐ **If NO, skip to section 9 PHYSICAL AGENTS.**

If YES, provide the following:

a. Identify radioactive source(s): _____

b. Radiation Safety Committee Approval (date): _____

VA License #: NRC 34-00203-03 ☐ CWRU License #: 34-00738-04 ☐

2. Are you currently approved to use radioisotopes? Yes ☐ No ☐

3. If not currently licensed, do you have in application in progress? Yes ☐ No ☐

4. If not currently licensed, under whose supervision will you perform operations involving the use of radioisotopes? _____

c. Additional information pertaining to use of Radioactive materials:

Radioisotope: _____ Maximum activity in laboratory at any given time: _____

Personnel who will work with Radioisotope: _____

Length of time radioisotope is considered a risk: _____

Means of Decontamination: _____

Monitoring methods: _____

Monitoring to be performed by: _____

*Radioactive waste is turned in to the Radiation Safety Officer, who segregates, packages, and manually compacts, if possible, and stores according to half-life. Long-lived radioactive waste is accumulated and then shipped to a nuclear repository via licensed radioactive waste broker.

**NOTE: If Iodine is used, will compounds be in volatile form and/or used in radioiodination?* Yes ☐ No ☐

If yes, specify where: Location: _____ Building: _____ Room # _____
(Use of radioisotopes in human research subjects is not currently allowed at the Cleveland VAMC.)

Will radioisotopes be used in humans at an alternate institution? Yes ☐ No ☐

If yes, specify where: Location: _____ Building: _____ Room # _____

9. PHYSICAL AGENTS

Does your research involve Physical Agents? Yes ☐ No ☐ **If NO, skip to section 10 PHYSICAL HAZARDS.**

If yes, provide the following:

a. Electrical Device Yes ☐ No ☐
Trauma to Animals Yes ☐ No ☐
Other ☐ specify: _____

b. Has the electrical device been approved for its intended use? Yes ☐ (attach approval notice)
Not Applicable ☐

c. Explain hazard: _____

10. PHYSICAL HAZARDS

Physical hazards are addressed in the facility Occupational Safety and Health Plan.

With regard to any of the potential hazards identified in this form, training will be provided to laboratory staff in: (1) Coordination with facility safety officials; (2) Practices and techniques required to ensure safety; (3) Procedures for dealing with accidents. Medical Research Service has the following Medical Research Service Policies in place that address all the above:

151-A New Employee Training Policy
151-B Fire and Fire Drill Procedure
151-C Storage Procedures for Common Storage Areas
151-D Laboratory Moving Policy
151-E Laboratory Decommissioning Policy
151-H Biosafety Policy
151-I Medical Research Service Safety Program
151-J Hazard Assessment and PPE Training Program
151-K Office Safety Policy
151-L Lockout/Tagout Policy

151-F Utility Failure Procedure
151-G Eating and Drinking Policy
151-M Emergency Preparedness Procedure
151-N Employee Training by Supervisor Policy
151-O Emergency Protocol for the Animal Research Facility

The Medical Research Service Safety Training Module with Chemical Hygiene Plan and Hazard Communication Program is available in each laboratory at the VA Medical Center.

All new employees in Research Service are required to attend a safety in-service. ALL employees must annually fulfill Medical Research and Medical Center safety training requirements.

All employees who use radioisotopes are required to participate in an orientation program, as well as annual reviews. This program is conducted by the medical center Radiation Safety Officer who is an employee of Nuclear Medicine Service. Case Western Reserve University has a similar training program.

Acknowledgement of Responsibility and Knowledge

I certify that my research studies will be conducted in compliance with and full knowledge of Federal, State, and local policies, regulations, and CDC-NIH Guidelines governing the use of, biohazardous materials, chemicals, radioisotopes, and physical hazards. I further certify that all technical and incidental workers involved with my

research studies will be aware of potential hazards, the degree of personal risk (if any), and will receive instructions and training on the proper handling and use of biohazardous materials, chemicals, radioisotopes, and physical hazards. A chemical inventory of all Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA)-regulated hazardous chemicals is attached to this survey.

Principal Investigator's Signature:_____ Date:_____

Certification of Safety Officer's Approval

A complete list of chemicals to be used in the proposal has been reviewed. Appropriate occupational safety and health, environmental, and emergency response programs will be implemented on the basis of the list provided.

Safety Officer's Signature:_____ Date:_____

John M. Schaffer, B.A.

Certification of Research Approval

The safety information for this application has been reviewed and is in compliance with Federal, State, and local policies, regulations, and CDC-NIH Guidelines governing the use of biohazardous materials, chemicals, radioisotopes, and physical hazards. Copies of any additional surveys used locally are available from the Research and Development (R&D) Office.

Chair,
Subcommittee on Research Safety:_____ **Date:**_____
John M. Schaffer, B.A.

Chair,
Subcommittee on Biosafety: _____ **Date:**_____
Curtis J. Donskey, M.D.

Chair,
Research & Development Committee: _____ **Date:**_____
Neal S. Peachey, Ph.D.

Radiation Safety Officer: **Not applicable.** **Date:**_____
(If applicable) **Steven W. Landgraf, M.A.**

Facility Safety Officer:_____ **Date:**_____
James M. Rummer, M.S.